## FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT APPLICATION NO.: 10/023,909 ATTY. DOCKET NO.: C1039.70058US00 FILING DATE: December 18, 2001 CONFIRMATION NO.: 8458 APPLICANT: Davis et al. GROUP ART UNIT: 1648 EXAMINER: Jeffrey S. Parkin

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## U.S. PATENT DOCUMENTS

Maniner'sold	Cite	U.S. Patent Docum	ent	Name of Patentee or Applicant of Cited	Date of Publication or Issue	
Initials	No.	Number	Kind Code	Document	of Cited Document MM-DD-YYYY	
7	A109	5,075,109		Tice et al.	12-24-1991	
$\sigma_{\perp}$	A110	5,543,152		Webb et al.	08-06-1996	
	A111	5,595,756		Bally et al.	01-21-1997	
•	A112	5,663,153		Hutcherson et al.	09-02-1997	
	A113	5,679,647		Carson et al.	10-21-1997	
	A114	5,705,385		Bally et al.	01-06-1998	
	A115	5,723,335		Hutcherson et al.	03-03-1998	
	A116	5,736,152		Dunn	04-07-1998	
	A117	5,753,613		Ansell et al.	05-19-1998	
	A118	5,766,920		Babbitt et al.	06-16-1998	
	A119	5,780,448		Davis	07-14-1998	
	A120	5,814,335		Webb et al.	09-29-1998	
	A121	5,965,542		Wasan et al.	10-12-1999	
	A122	5,976,567		Wheeler et al.	11-02-1999	
	A123	5,981,501		Wheeler et al.	11-09-1999	
	A124	6,004,534		Langer et al.	12-21-1999・	
	A125	6,027,726		Ansell	02-22-2000	
	A126	6,030,954		Wu et al.	02-29-2000	
	A127	6,042,838		Briles et al.	03-28-2000	
	A128	6,086,898		DeKruyff et al.	07-11-2000	
	A129	6,090,791		Sato et al.	07-18-2000	
	A130	6,110,745		Zhang et al.	08-29-2000	
	A131	6,221,882	B1	Macfarlane	04-24-2001	
	A132	6,225,292	B1	Raz et al.	05-01-2001	
	A133	6,248,720	B1	Mathiowitz et al.	06-19-2001	
	A134	6,399,630	Bl	Macfarlane	06-04-2002	
	A135	6,479,504	B1	Macfarlane et al.	11-12-2002	
	A136	6,498,148	BI	Raz	12-24-2002	
	A137	6,521,637	B2	Macfarlane	02-18-2003	
	A138	6,610,308	Bi	Haensler	08-26-2003	
4	A139	6,620,805	Bl	Takle et al.	09-16-2003	
<b>P</b>	A140	6,693,086	Bi	Dow et al.	02-17-2004	

EXAMINER:		DATE CONSIDERED:
	2	12/24/07

<sup>\*</sup> EXAMINER: Initial Section of this form with next communication to Applicant.

EODM DTO	1440/A and B (s	modified P	TO/SR/08)	APPLICATION N	IO.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00		
FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE				FILING DATE:	December 18, 2001	CONFIRMATION	CONFIRMATION NO.: 8458	
STATEMENT BY APPLICANT			APPLICANT:	Davis et al.				
Sheet 2 of 12				GROUP ART UN	IT: 1648	EXAMINER:	Jeffrey S. Parkin	

7	A141	6,737,066	B1	Moss	05-18-2004
0,	A142	6,821,957	Bl	Krieg et al.	11-23-2004
	A143	6,835,395	B1	Semple et al.	12-28-2004
	A144	6,893,821	B2	Raz et al.	05-17-2005
	A145	6,943,240	B2	Bauer et al.	09-13-2005
	A146	6,949,520	B1	Hartmann et al.	09-27-2005
	A147	7,001,890	Bl	Wagner et al.	02-21-2006
	A148	7,049,302	B1	Kensil	05-23-2006
	A149	7,129,222	B2	Van Nest et al.	10-31-2006
	A150	7,223,741	B2	Krieg	05-29-2007
	A151	2001-0034330	Αl	Kensil	10-25-2001
	A152	2002-0009457	Al	Bowersock et al.	01-24-2002
	A153	2003-0078223	Al	Raz et al.	04-24-2003
	A154	2003-0092663	Al	Raz et al.	05-15-2003
	A155	2003-0104044	Al	Semple et al.	06-05-2003
	A156	2003-0119774	Al	Foldvari et al.	06-26-2003
	A157	2003-0165478	Al	Sokoll et al.	09-04-2003
	A158	2003-0232856	Al	Macfarlane	12-18-2003
	A159	2004-0013688	Al	Wise et al.	01-22-2004
	A160	2004-0006010	Al	Carson et al.	01-08-2004
	A161	2004-0047869	Al	Garcon et al.	03-11-2004
	A162	2004-0067902	A9	Bratzler et al.	04-08-2004
	A163	2004-0092468	Al	Schwartz et al.	05-13-2004
	A164	2004-0198680	Al	Krieg	10-07-2004
	A165	2004-0229835	Al	Krieg et al.	11-18-2004
	A166	2004-0234512	Al	Wagner et al.	11-25-2004
	A167	2004-0235770	Al	Davis et al.	11-25-2004
	A168	2004-0235774	Al	Bratzler et al.	11-25-2004
	A169	2004-0235777	Al	Wagner et al.	11-25-2004
	A170	2004-0235778	Al	Wagner et al.	11-25-2004
	A171	2004-0247662	Al	Dow et al.	12-09-2004
	A172	2004-0266719	Al	McCluskie et al.	12-30-2004
	A173	2005-0004061	Al	Krieg et al.	01-06-2005
	A174	2005-0004062	A1	Krieg et al.	01-06-2005
	A175	2005-0009774	A1	Krieg et al.	01-13-2005
<b>T</b>	A176	2005-0013812	Al	Dow et al.	01-20-2005

EXAMINER: DATE CONSIDERED	·
$\Sigma$ – $\Omega$	12/24/07

EXAMINER: Initial if eference considered, whether or noticitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION N	O.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			FILING DATE:	December 18, 2001	CONFIRMATION	CONFIRMATION NO.: 8458	
			APPLICANT:	Davis et al.			
			GROUP ART UNIT: 1648		EXAMINER:	Jeffrey S. Parkin	
Sheet	3	of	12	GROOF ART ON	11. 1046	EAAMINER.	

	,		,		
	A177	2005-0032734	Al	Davis et al.	02-10-2005
	A178	2005-0032736	Al	Krieg et al.	02-10-2005
	A179	2005-0037403	A1	Krieg et al.	02-17-2005
	A180	2005-0037985	Al	Krieg et al.	02-17-2005
	A181	2005-0043529	A1.	Davis et al.	02-24-2005
	A182	2005-0049215	A1	Krieg et al.	03-03-2005
	A183	2005-0049216	A1	Krieg et al.	03-03-2005
· 1	A184	2005-0054601	A1	Wagner et al.	03-10-2005
	A185	2005-0054602	Al	Krieg et al.	03-10-2005
	A186	2005-0059619	A1	Krieg et al.	03-17-2005
	A187	2005-0059625	A1	Krieg et al.	03-17-2005
•	A188	2005-0070491	A1	Krieg et al.	03-31-2005
	A189	2005-0075302	A1	Hutcherson et al.	04-07-2005
	A190	2005-0100983	A1	Bauer et al.	05-12-2005
	A191	2005-0101554	Al	Krieg et al.	05-12-2005
	A192	2005-0101557	A1	Krieg et al.	05-12-2005
	A193	2005-0119273	A1	Lipford et al.	06-02-2005
	A194	2005-0123523	A1	Krieg et al.	06-09-2005
	A195	2005-0130911	A1	Uhlmann et al.	06-16-2005
	A196	2005-0148537	Al	Krieg et al.	07-07-2005
	A197	2005-0169888	Al	Hartman et al.	08-04-2005
	A198	2005-0171047	Al	Krieg et al.	08-04-2005
	A199	2005-0176672	A1 .	Scheule et al.	08-11-2005
	A200	2005-0181422	Al	Bauer et al.	08-18-2005
	A201	2005-0182017	Al ·	Krieg	08-18-2005
	A202	2005-0191342	Al	Tam et al.	09-01-2005
	A203	2005-0197314	Al	Krieg et al.	09-08-2005
	A204	2005-0209184	Al	Klinman et al.	09-22-2005
	A205	2005-0214355	A1	Klinman et al.	09-29-2005
	A206	2005-0215501	A1	Lipford et al.	09-29-2005
	A207	2005-0233995	Al	Krieg et al.	10-20-2005
	A208	2005-0233999	Al .	Krieg et al.	10-20-2005
	A209	2005-0239732	Al	Krieg et al.	10-27-2005
	A210	2005-0239733	Al	Jurk et al.	10-27-2005
	A211	2005-0239734	Al	Uhlmann et al.	10-27-2005
¥	`A212	2005-0239736	Al	Krieg et al.	10-27-2005

EXAMINER:	DATE CONSIDERED:
	12/24/07

<sup>#</sup> EXAMINER: Initial if reference considered, whether or noticitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE				APPLICATION NO	D.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00	
				FILING DATE:	DATE: December 18, 2001 CONFIRMATION NO.: 8458		
STATEMENT BY APPLICANT			APPLICANT:	Davis et al.			
				CDOUB ART INII	г: 1648	EXAMINER:	Jeffrey S. Parkin
Sheet	4	of	12	GROUP ART UNIT: 1648		EAAWIINER:	Jeiney S. Paikiii

7	A213	2005-0244379	A1	Krieg et al.	11-03-2005
0,	A214	2005-0244380	Al	Krieg et al.	11-03-2005
	A215	2005-0245477	Al	Krieg et al.	11-03-2005
	A216	2005-0249794	A1	Semple et al.	11-10-2005
	A217	2005-0250726	Al	Krieg et al.	11-10-2005
	A218	2005-0256073	Al	Lipford et al.	11-17-2005
	A219	2005-0267064	Al	Krieg et al.	12-01-2005
•	A220	2005-0277604	Al	Krieg et al.	12-15-2005
	A221	2005-0277609	A1	Krieg et al.	12-15-2005
	A222	2006-0003955	Al	Krieg et al.	01-05-2006
	A223	2006-0003962	Al	Ahluwalia et al.	01-05-2006
1	A224	2006-0019916	A1	Krieg et al.	01-26-2006
7	A225	2006-0019923	Al	Davis et al.	01-26-2006
	A226	2006-0058251	A1	Krieg et al.	03-16-2006
	A227	2006-0089326	Al	Krieg et al.	04-27-2006
	A228	2006-0094683	Al	Krieg et al.	05-04-2006
	A229	2006-0140875	A1	Krieg et al.	06-29-2006
	A230	2006-0154890	A1	Bratzler et al.	07-13-2006
	A231	2006-0172966	Al	Lipford et al.	08-03-2006
	A232	2006-0188913	Al	Krieg et al.	08-24-2006
	A233	2006-0211639	Al	Bratzler et al.	09-21-2006
	A234	2006-0211644	Al	Krieg et al.	09-21-2006
	A235	2006-0223769	Al	Dow et al.	10-05-2006
	A236	2006-0229271	Al	Krieg et al.	10-12-2006
	A237	2006-0241076	Al	Uhlmann et al.	10-26-2006
	A238	2006-0246035	Al	Ahluwalia et al.	11-02-2006
	A239	2006-0251623	Al	Bachmann et al.	11-09-2006
	A240	2006-0251677	A1	Bachmann et al.	11-09-2006
	A241	2006-0286070	Al	Hartmann et al.	12-21-2006
ĺ	A242	2006-0287263	Al	Davis et al.	12-21-2006
	A243	2007-0009482	A1	Krieg et al.	01-11-2007
	A244	2007-0010470	Al	Krieg et al.	01-11-2007
	A245	2007-0037767	Al	Bratzler et al.	02-15-2007
	A246	2007-0065467	A1	Krieg et al.	03-22-2007
	A247	2007-0066553	Al	Krieg et al.	03-22-2007
4	A248	2007-0066554	Al	Krieg et al.	03-22-2007

EXAMINER:	DATE CONSIDERED:
<b>\</b>	12/2/22
	12 24 (8)

EXAMINER: Initial if reference considered, whether or notictation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION N	D.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			FILING DATE:	December 18, 2001	CONFIRMATION	CONFIRMATION NO.: 8458	
			APPLICANT:	Davis et al.			
			GROUP ART UNIT: 1648		EXAMINER:	Jeffrey S. Parkin	
Sheet	5	of	12	GROUP ART UNI	1: 1046	EAAMINER:	Jeffley S. Parkill

$\overline{\mathcal{M}}$	A249	2007-0078104	A1	Krieg et al.	04-05-2007
01	A250	2007-0129320	A9	Davis et al.	06-07-2007
	A251	2007-0142315	Al	Forsbach et al.	06-21-2007
	A252	2007-0184465	A1	Wagner et al.	08-09-2007
	A253	2007-0202128	Al	Krieg et al.	08-30-2007

## FOREIGN PATENT DOCUMENTS

Examiner's	Cite	Cite No. Office/ Country Number Kind Code Number Code Name of Patentee or Applicant of Cited Document		ent	Name of Patentee or Applicant of Cited	Date of Publication of	Translation
Initials #				Cited Document MM-DD-YYYY	(Y/N)		
	B27	WO	98/29557	Al	Biovector Therapeutics	07-09-1998	
Oi	B28	wo	98/51278	A2	INEX Pharmaceuticals Corp.	11-19-1998	
	B29	wo	99/30686	Al	INEX Pharmaceuticals Corporation	06-24-1999	
	B30	WO	99/33493	A1	INEX Pharmaceuticals Corporation	07-08-1999	
	B31	WO	99/33868	A2	SmithKline Beecham Biologicals, S.A.	07-08-1999	
	B32	wo	99/43350	Al	IOMAI Corporation	09-02-1999	
	B33	WO	99/52549	Al	SmithKline Beecham Biologicals S.A.	10-29-1999	
	B34	wo	99/55743	Al	INEX Pharmaceuticals Corporation	11-04-1999	
	B35	wo	00/06588	Al	University of Iowa Research Foundation	02-10-2000	
	B36	wo	00/14217	A2	CPG Immunopharmaceuticals GMBH	03-16-2000	
	B37	wo	00/67023	Al	CPG Immunopharmaceuticals GMBH	11-09-2000	
•	B38	wo	2004/026888	A2	Coley Pharmaceutical GMBH	04-01-2004	
	B39	wo	2004/094671	A2	Coley Pharmaceutical GMBH	11-04-2004	
	B40	wo	2006/080946	A2	Coley Pharmaceutical GMBH	08-03-2006	
	B41	wo	2007/031877	A2	Coley Pharmaceutical GMBH	03-22-2007	
	B42	WO	2007/038720	A2	Coley Pharmaceutical GMBH	04-05-2007	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
X	C26	Press Release, January 2007, "Coley Pharmaceutical Group Updates Hepatitis C Drug Development Strategy".	
8	- C27	Press Release, June 2007, "Coley Pharmaceutical Group Announces Pfizer's Discontinuation of Clinical Trials for PF-3512676 Combined with Cytotoxic Chemotherapy in Advanced Non Small Cell Lung Cancer".	

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EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO	1449/A and B (m	odified F	TO/SB/08)	APPLICATION NO	.: 10/023,909	ATTY. DOCKET N	NO.: C1039.70058US00
	RMATION D			FILING DATE:	December 18, 2001	CONFIRMATION	NO.: 8458
	EMENT BY			APPLICANT:	Davis et al.		
Sheet	6	of	12	GROUP ART UNIT	: 1648	EXAMINER:	Jeffrey S. Parkin

$\square$	C28	AGRAWAL et al., Pharmacokinetics of antisense oligonucleotides. Clin Pharmacokinet. 1995  Jan;28(1):7-16.	
	C29	AGRAWAL et al., Chapter 19: Pharmacokinetics and bioavailability of antisense oligonucleotides following oral and colorectal administrations in experimental animals. 1998: 525-43.	
	C30	AGRAWAL et al., Antisense oligonucleotides: towards clinical trials. Trends in Biotechnology, 1996; 14: 376-87.	
	C31	ALPAR et al., Potential of particulate carriers for the mucosal delivery of DNA vaccines. Biochem Soc Trans. 1997 May;25(2):337S.	
	C32	ANITESCU et al., Interleukin-10 functions in vitro and in vivo to inhibit bacterial DNA-induced secretion of interleukin-12. J Interferon Cytokine Res. 1997 Dec;17(12):781-8.	
	C33	BAUER et al., DNA activates human immune cells through a CpG sequence-dependent manner. Immunology. 1999 Aug;97(4):699-705.	
	C34	BENNETT, Intracellular delivery of oligonucleotides with cationic liposomes. In: Delivery Strategies for Antisense Oligonucleotide Therapeutics. Akthar, Ed. 1995:223-32.	
	C35	BOWERSOCK et al., Evaluation of an orally administered vaccine, using hydrogels containing bacterial exotoxins of Pasteurella haemolytica, in cattle. Am J Vet Res. 1994 Apr;55(4):502-9.	
	C36	BRAZOLOT MILLAN et al., CpG DNA can induce strong Th1 humoral and cell-mediated immune responses against hepatitis B surface antigen in young mice. Proc Natl Acad Sci U S A. 1998 Dec 22;95(26):15553-8.	
	C37	BROIDE et al., DNA-Based immunization for asthma. Int Arch Allergy Immunol. 1999 Feb- Apr;118(2-4):453-6.	
	C38	CARSON et al., Oligonucleotide adjuvants for T helper 1 (Th1)-specific vaccination. J Exp Med. 1997 Nov 17;186(10):1621-2.	
	C39	CHACE et al., Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. Clin Immunol Immunopathol. 1997 Aug;84(2):185-93.	
	C40	CHELVARAJAN et al., CpG oligodeoxynucleotides overcome the unresponsiveness of neonatal B cells to stimulation with the thymus-independent stimuli anti-IgM and TNP-Ficoll. Eur J Immunol. 1999 Sep;29(9):2808-18.	
	C41	CHEN et al., Protective immunity induced by oral immunization with a rotavirus DNA vaccine encapsulated in microparticles. J Virol. 1998 Jul;72(7):5757-61.	
	C42	CHU et al., CpG oligodeoxynucleotides down-regulate macrophage class II MHC antigen processing. J Immunol. 1999 Aug 1;163(3):1188-94.	
	C43	CROOKE et al., Phosphorothioate Oligonucleotides. Therapeut Apps. 1995;ch5:63-84.	
	C44	CRYZ et al., European Commission COST/STD Initiative. Report of the expert panel VII. Vaccine delivery systems. Vaccine. 1996 May;14(7):665-90.	
	C45	DAVIS et al., DNA vaccines for prophylactic or therapeutic immunization against hepatitis B virus.  Mt Sinai J Med. 1999 Mar;66(2):84-90. Review.	
	C46	DELONG et al., Characterization of complexes of oligonucleotides with polyamidoamine starburst dendrimers and effects on intracellular delivery. J Pharm Sci. 1997 Jun;86(6):762-4. Abstract Only.	
	C47	ELDRIDGE et al., Biodegradable microspheres as a vaccine delivery system. Mol Immunol. 1991 Mar;28(3):287-94. Abstract Only.	
4	C48	EMI et al., Gene transfer mediated by polyarginine requires a formation of big carrier-complex of DNA aggregate. Biochem Biophys Res Commun. 1997 Feb 13;231(2):421-4.	

EXAMINER:		DATE CONSIDERED:		,
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]	<del>\</del>	12.	24	87
			27	0/

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

EORM PTO	0-1449/A and B (m	odifie	H PTO/SR/08)	APPLICATION NO.: 10/023,909		ATTY. DOCKET NO.: C1039.70058US00	
	RMATION I		·	FILING DATE:	December 18, 2001	CONFIRMATION	NO.: 8458
	EMENT BY			APPLICANT:	Davis et al.		
				GROUP ART UNI	T: 1648	EXAMINER:	Jeffrey S. Parkin
Sheet	7	of	12	GROOT ART ON	11. 1070	EARWINGK.	

X	C49	ETCHART et al., Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin. J Gen Virol. 1997 Jul;78 ( Pt 7):1577-80.	
1	C50	FILION et al., Major limitations in the use of cationic liposomes for DNA delivery. Int J Pharmaceut. 1998; 162:159-70.	
	C51	FRALEY et al., New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids. Trends Biochem Sci. 1981;6:77-80.	
	C52	GALLICHAN et al., Specific secretory immune responses in the female genital tract following intranasal immunization with a recombinant adenovirus expressing glycoprotein B of herpes simplex virus. Vaccine. 1995 Nov;13(16):1589-95.	
	C53	GEISSLER et al., Enhancement of cellular and humoral immune responses to hepatitis C virus core protein using DNA-based vaccines augmented with cytokine-expressing plasmids. J Immunol. 1997 Feb 1;158(3):1231-7.	
	C54	GRAMZINSKI et al., Immune response to a hepatitis B DNA vaccine in Aotus monkeys: a comparison of vaccine formulation, route, and method of administration. Mol Med. 1998 Feb;4(2):109-18.	
·	C55	GREGORIADIS et al., Liposomes for drugs and vaccines. Trends Biotechnol. 1985;3:235-41.	
	C56	GREGORIADIS et al., Engineering liposomes for drug delivery: progress and problems. Trends Biotechnol. 1995 Dec;13(12):527-37.	
	C57	HANEBERG et al., Induction of specific immunoglobulin A in the small intestine, colon-rectum, and vagina measured by a new method for collection of secretions from local mucosal surfaces. Infect Immun. 1994 Jan;62(1):15-23.	•
	C58	HARTMANN et al., CpG DNA and LPS induce distinct patterns of activation in human monocytes. Gene Ther. 1999 May;6(5):893-903.	
	C59	HARTMANN et al., Spontaneous and cationic lipid-mediated uptake of antisense oligonucleotides in human monocytes and lymphocytes. J Pharmacol Exp Ther. 1998 May;285(2):920-8.	
	C60	HARTMANN et al., CpG DNA: a potent signal for growth, activation, and maturation of human dendritic cells. Proc Natl Acad Sci U S A. 1999 Aug 3;96(16):9305-10.	•
	C61	HAYNES et al., Particle-mediated nucleic acid immunization. J Biotechnol. 1996 Jan 26;44(1-3):37-42.	
	C62	HEDLEY et al., Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses. Nat Med. 1998 Mar;4(3):365-8.	
	C63	HOLMGREN et al., Cholera toxin and cholera B subunit as oral-mucosal adjuvant and antigen vector systems. Vaccine. 1993 Sep;11(12):1179-84.	
	C64	HOPKIN et al., Curbing the CpGs of Bacterial and Viral DNA. BioMedNet. 1999 Jun25; Issue 57.	
	C65	HORNQUIST et al., Cholera toxin adjuvant greatly promotes antigen priming of T cells. Eur J Immunol. 1993 Sep;23(9):2136-43.	
	C66	HUANG et al., Induction and regulation of Th1-inducing cytokines by bacterial DNA, lipopolysaccharide, and heat-inactivated bacteria. Infect Immun. 1999 Dec;67(12):6257-63.	
1	C67	HUDSON et al., Nucleic acid dendrimers: Novel biopolymer structures. J Am Chem Soc. 1993;115:2119-24.	

EXAMINER:	DATE CONSIDERED:	,	
9	1	J	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or notcitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/0	APPLICATION NO.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00
INFORMATION DISCLOSUR	FILING DATE: December 18, 2001	CONFIRMATION NO.: 8458
STATEMENT BY APPLICAN'	APPLICANT: Davis et al.	
	GROUP ART UNIT: 1648	EXAMINER: Jeffrey S. Parkin
Sheet 8 of 12	GROUP ART UNIT: 1048	EARMINER. Jeiney S. Faikin

directly on human NK and activated T cells to induce IFN-gamma production in vitro. J Immunol. 1999 Oct 1;163(7):3642-52.  C69 JAKOB et al., Activation of cutaneous dendritic cells by CpG-containing oligodeoxynucleotides: a role for dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA. J Immunol. 1998 Sep 1;516(6):3042-9.  C70 JAKOB et al., Bacterial DNA and CpG-containing oligodeoxynucleotides activate cutaneous dendritic cells and induce 1L-12 production: implications for the augmentation of Th1 responses. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4)457-61.  C71 JONES et al., Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun;15(8):814-7.  C72 JONES et al., Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Actus monkeys. Vaccine. 1999 Aug 6;17(23-24):3065-71.  C73 KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose. Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.  C74 KLIMMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLIMMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.  C76 KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 58th National Scientific Meeting. Minneapolis, Minnesola, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C88 KRIEG et al., Dan-Feb;1(1):56-63.  C80 KRIEG et al., Educations of immune stimulatory CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Cane. 1999 Oct; 35/Suppl-8:110				
role for dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA. J Immunol. 1998 Sep 15;161(6):3042-9.  C70 JAKOB et al., Bacterial DNA and CpG-containing oligodeoxynucleotides activate cutaneous dendritic cells and induce IL-12 production: implications for the augmentation of Th1 responses. Int Arch Allergy Immunol. 1999 Feb.Apr;118(2-4):457-61.  C71 JONES et al., Poly(DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun;15(8):814-7.  C72 JONES et al., Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys. Vaccine. 1999 Aug 6;17(23-24):3065-71.  C73 KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose. Jpn J Med Sci Biol. 1990 Cty;43(5):171-82.  C74 KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLINMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.  C76 KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 38h National Scientific Meeting, Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan;eti(1):15-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:510. Abstract #14.  C79 KRIEG et al., Heaptor and the stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Hechanism and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Ac	d	C68	1999 Oct 1;163(7):3642-52.	
dendritic cells and induce IL-12 production: implications for the augmentation of Th1 responses. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4):457-61.  C71 JONES et al., Poly(DL-lacitide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun;15(8):814-7.  C72 JONES et al., Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys. Vaccine. 1999 Aug 6;17(23-24):3065-71.  C73 KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose. Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.  C74 KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 58 <sup>th</sup> National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl.).  C77 KRIEG et al., Direct immunologic activities of CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Applications of immune stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998;243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications for clinical immunology. BioDrugs. 1998 Nov 1;10(5	1		role for dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA. J Immunol. 1998 Sep 15;161(6):3042-9.	
mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997 Jun;15(8):814-7.  C72 JONES et al., Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys. Vaccine. 1999 Aug 6;17(23-24):3065-71.  C73 KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose. Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.  C74 KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLINMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.  C76 KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 58 <sup>th</sup> National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Cane. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Det 0;1;489(1):107-16.  C82 KRIEG et al., Mechanisms and therapeutic applications of immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 K		C70	dendritic cells and induce IL-12 production: implications for the augmentation of Th1 responses. Int	
peptide malaria vaccine in Aotus monkeys. Vaccine. 1999 Aug 6;17(23-24):3065-71.  C73 KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose. Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.  C74 KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLINMAN et al., Cpg motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.  C76 KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated Cpg motifs. American College of Rheumatology 58 <sup>th</sup> National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C84 KRIEG et al., Mechanisms and interapeutic applications of immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 199		C71	mucosal antibody responses to encoded protein after oral administration. Vaccine. 1997	•
acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose. Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.  C74 KLINMAN et al., Therapeutic applications of CpG-containing oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLINMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.  KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 58th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C84 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C85 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C72		
Nucleic Acid Drug Dev. 1998 Apr;8(2):181-4.  C75 KLINMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.  C76 KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 58th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanism and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.		C73	acid from Mycobacterium bovis BCG complexed with poly-L-lysine and carboxymethylcellulose.  Jpn J Med Sci Biol. 1990 Oct;43(5):171-82.	
C76 KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel un-methylated CpG motifs. American College of Rheumatology 58th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigennonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.		C74		
un-methylated CpG motifs. American College of Rheumatology 58th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).  C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C75	KLINMAN et al., CpG motifs as immune adjuvants. Vaccine. 1999 Jan;17(1):19-25.	
C77 KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.  C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C76	un-methylated CpG motifs. American College of Rheumatology 58th National Scientific Meeting.	
C78 KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen- nonspecific cancer immunotherapy. Eur J Canc. 1999 Oct; 35/Suppl4:S10. Abstract #14.  C79 KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C77	KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene	
Application. Crooke, Ed. 1998:243-62.  C80 KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996:116.  C81 KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.  C82 KRIEG et al., The CpG motif: Implications for clinical immunology. BioDrugs. 1998 Nov 1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C78	KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-	
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1;10(5):341-6.  C83 KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.  C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C81	Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.	
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C84 KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. Pharmacol Ther. 1999 Nov;84(2):113-20.  C85 KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C83		
motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.  C86 KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.		C84	KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA.	
		C85		
		C86	KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.	
	7	C87	KRIEG et al., Infection. In: McGraw Hill Book. 1996:242-3.	*

EXAMINER:	DATE CONSIDERED:
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EXAMINER: Initial if reference considered, whether or notitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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Sheet 9 of 12			

C88	KRIEG et al., Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA. Trends Microbiol. 1996 Feb;4(2):73-6.	
C89	KRIEG, Therapeutic potential of Toll-like receptor 9 activation. Nat Rev Drug Discov. 2006 Jun;5(6):471-84.	
C90	Starburst polyamidoamine dendrimers. Proc Natl Acad Sci U S A. 1996 May 14;93(10):4897-902.	
C91	intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. Cancer Immunol Immunother. 1992;34(5):283-8.	
C92	course of regression induced by injections of a BCG nucleic acid fraction. Int J Immunopharmacol. 1992 Jul;14(5):773-82.	
C93	KURAMOTO et al., In situ infiltration of natural killer-like cells induced by intradermal injection of the nucleic acid fraction from BCG. Microbiol Immunol. 1989;33(11):929-40.	
C94	LeCLERC et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. Cell Immunol. 1997 Aug 1;179(2):97-106.	
C95	LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. Immunology. 1998 Jul;94(3):285-9.	
C96	inhibitors of replication of human immunodeficiency virus in cell culture. Proc Natl Acad Sci U S A. 1989 Sep;86(17):6553-6.	·
C97	Ser. 1991;(24):75-8.	
C98	responses to protein antigen: a new class of vaccine adjuvants. Eur J Immunol. 1997	
C99	LITZINGER et al., Fate of cationic liposomes and their complex with oligonucleotide in vivo.  Biochim Biophys Acta. 1996 Jun 11;1281(2):139-49.	
C100	vaccine strategies involving granulocyte-macrophage colony-stimulating factor. Blood. 1998 Nov 15;92(10):3730-6.	
C101	1997 Sept7;45(7):333A.	
C102	LIU et al., Immunization of non-human primates with DNA vaccines. Vaccine. 1997 Jun;15(8):909-12.	
C103	MacGREGOR et al., First human trial of a DNA-based vaccine for treatment of human immunodeficiency virus type 1 infection: safety and host response. J Infect Dis. 1998 Jul;178(1):92-100.	
C104	MALOY et al., Induction of Th1 and Th2 CD4+ T cell responses by oral or parenteral immunization with ISCOMS. Eur J Immunol. 1995 Oct;25(10):2835-41.	
C105	MARTIN-OROZCO et al., Enhancement of antigen-presenting cell surface molecules involved in cognate interactions by immunostimulatory DNA sequences. Int Immunol. 1999 Jul;11(7):1111-8.	
	C89 C90 C91 C92 C93 C94 C95 C96 C97 C98 C100 C101 C102 C103	Microbiol. 1996 Feb;4(2):73-6.  C89 KRIEG, Therapeutic potential of Toll-like receptor 9 activation. Nat Rev Drug Discov. 2006 Jun;5(6):471-84.  C90 KUKOWSKA-LATALLO et al., Efficient transfer of genetic material into mammalian cells using Starburst polyamidoamine dendrimers. Proc Natl Acad Sci U S A. 1996 May 14;93(10):4897-902.  C91 KURAMOTO et al., Induction of T-cell-mediated immunity against MethA fibrosarcoma by intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. Cancer Immunol Immunother. 1992;34(5):283-8.  C92 KURAMOTO et al., Changes of host cell infiltration into Meth A fibrosarcoma tumor during the course of regression induced by injections of a BCG nucleic acid fraction. Int J Immunopharmacol. 1992 Jul;14(5):773-82.  C93 KURAMOTO et al., In situ infiltration of natural killer-like cells induced by intradermal injection of the nucleic acid fraction from BCG. Microbiol Immunol. 1989;33(11):929-40.  C94 LeclerC et al., The preferential induction of a Th1 immune response by DNA-based immunization is mediated by the immunostimulatory effect of plasmid DNA. Cell Immunol. 1997 Aug 1;179(2):97-106.  C95 LeE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. Immunology. 1998 Jul;94(3):285-9.  C96 LETSINGER et al., Cholesteryl-conjugated oligonucleotides: synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture. Proc Natl Acad Sci U S A. 1989 Sep;86(17):6553-6.  C97 LETSINGER et al., Synthesis and properties of modified oligonucleotides. Nucleic Acids Symp Ser. 1991;(24):75-8.  C98 LIPFORD et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. Eur J Immunol. 1997 Sep;27(9):2340-4.  C101 LiU et al., Immunostimulatory CpG oligodeoxynucleotides enhance the immune response to vaccine strategies involving granulocyte-macrophage colony-stimulating factor. Blood. 1

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FORM PTC	1-1449/A and R (m	odifie	ŧ PT∩/SR/0\$\	APPLICATION NO.: 10/023,909		ATTY. DOCKET NO.: C1039.70058US00	
FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE				FILING DATE: Dec	ember 18, 2001	CONFIRMATION NO	.: 8458
	STATEMENT BY APPLICANT			APPLICANT: D	Davis et al.		-
				GROUP ART UNIT: 1	648	EXAMINER:	Jeffrey S. Parkin
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<b>&gt;~</b>		C106	McCLUSKIE et al., CpG DNA as mucosal adjuvant. Immunol Letts. 1999;69(1):30-1. Abstract #5.2
0		C107	McCLUSKIE et al., Novel strategies using DNA for the induction of mucosal immunity. Crit Rev Immunol. 1999;19(4):303-29.
		C108	McCLUSKIE et al., Immunization against hepatitis B virus by mucosal administration of antigenantibody complexes. Viral Immunol. 1998;11(4):245-52.
•		C109	McCLUSKIE et al., Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates. Mol Med. 1999 May;5(5):287-300.
		C110	McCLUSKIE et al., Mucosal immunization with DNA vaccines. Microbes Infect. 1999 Jul;1(9):685-98.
		C111	McGHEE et al., The mucosal immune system: from fundamental concepts to vaccine development. Vaccine. 1992;10(2):75-88.
		C112	OKADA et al., Bone marrow-derived dendritic cells pulsed with a tumor-specific peptide elicit effective anti-tumor immunity against intracranial neoplasms. Int J Cancer. 1998 Oct 5;78(2):196-201.
		C113	OXENIUS et al., CpG-containing oligonucleotides are efficient adjuvants for induction of protective antiviral immune responses with T-cell peptide vaccines. J Virol. 1999 May;73(5):4120-6.
		C114	PISETSKY et al., Immunological properties of bacterial DNA. Ann N Y Acad Sci. 1995 Nov 27;772:152-63.
		C115	PISETSKY, The influence of base sequence on the immunostimulatory properties of DNA. Immunol Res. 1999;19(1):35-46.
		C116	PISETSKY et al., Immune activation by bacterial DNA: a new genetic code. Immunity. 1996 Oct;5(4):303-10.
		C117	PISETSKY et al., The influence of base sequence on the immunological properties of defined oligonucleotides. Immunopharmacology. 1998 Nov;40(3):199-208.
		C118	ROBERTSON et al., Crohn's trial shows the pros of antisense. Nat Biotechnol. 1997 Mar; 15(3):209.
		C119	ROBINSON, Nucleic acid vaccines: an overview. Vaccine. 1997 Jun;15(8):785-7.
		C120	SANDS et al., Biodistribution and metabolism of internally 3H-labeled oligonucleotides. I.  Comparison of a phosphodiester and a phosphorothioate. Mol Pharmacol. 1994 May;45(5):932-43.
		C121	SCHWARTZ et al., Bacterial DNA or oligonucleotides containing unmethylated CpG motifs can minimize lipopolysaccharide-induced inflammation in the lower respiratory tract through an IL-12-dependent pathway. J Immunol. 1999 Jul 1;163(1):224-31.
		C122	SIDMAN et al., Gamma-interferon is one of several direct B cell-maturing lymphokines. Nature. 1984 Jun 28-Jul 4;309(5971):801-4.
		C123	SONEHARA et al., Hexamer palindromic oligonucleotides with 5'-CG-3' motif(s) induce production of interferon. J Interferon Cytokine Res. 1996 Oct;16(10):799-803.
		C124	SPARWASSER et al., Bacterial DNA causes septic shock. Nature. 1997 Mar 27;386(6623):336-7.
		C125	SPARWASSER et al., Bacterial DNA and immunostimulatory CpG oligonucleotides trigger maturation and activation of murine dendritic cells. Eur J Immunol. 1998 Jun;28(6):2045-54.
4	,	C126	SPARWASSER et al., Immunostimulatory CpG-oligodeoxynucleotides cause extramedullary murine hemopoiesis. J Immunol. 1999 Feb 15;162(4):2368-74.

EXAMINER:		DATE CONSIDERED:	
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EXAMINER: Initial if reference considered, whether or notitation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO-1449/A and B (modified PTO/SB/08)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT				FILING DATE:	December 18, 2001	CONFIRMATION NO.	: 8458
				APPLICANT:	Davis et al.		
				GROUP ART UNIT:	1648	EXAMINER:	Jeffrey S. Parkin
Sheet 11 of 12			GROUP ART UNIT: 1848		EXAMINER. Jeffey S. Parkin		

$\Box$		C127	STAATS et al., Mucosal immunity to infection with implications for vaccine development. Curr Opin Immunol. 1994 Aug;6(4):572-83.	
	1	C128	STEIN et al., Problems in interpretation of data derived from in vitro and in vivo use of antisense oligodeoxynucleotides. Antisense Res Dev. 1994 Summer;4(2):67-9.	
		C129	STEIN et al., Non-antisense effects of oligodeoxynucleotides. Antisense Technology. 1997; ch11: 241-64.	
		C130	SUN et al. Type I interferon-mediated stimulation of T cells by CpG DNA. J Exp Med. 1998 Dec 21;188(12):2335-42.	
		C131	SUN et al., DNA as an adjuvant: capacity of insect DNA and synthetic oligodeoxynucleotides to augment T cell responses to specific antigen. Exp Med. 1998 Apr 6;187(7):1145-50.	
		C132	TACKET et al., Phase 1 safety and immune response studies of a DNA vaccine encoding hepatitis B surface antigen delivered by a gene delivery device. Vaccine. 1999 Jul 16;17(22):2826-9.	
		C133	TOKUNAGA et al., Synthetic oligonucleotides with particular base sequences from the cDNA encoding proteins of Mycobacterium bovis BCG induce interferons and activate natural killer cells. Microbiol Immunol. 1992;36(1):55-66.	
		C134	UGEN et al., DNA vaccination with HIV-1 expressing constructs elicits immune responses in humans. Vaccine. 1998 Nov;16(19):1818-21.	
		C135	VLASSOV et al., In Vivo pharmocokinetics of oligonucleotides following administration by different routes. CRC Press, Inc. Chapter 5. 1995:71-83.	
		C136	WANG et al., Induction of antigen-specific cytotoxic T lymphocytes in humans by a malaria DNA vaccine. Science. 1998 Oct 16;282(5388):476-80.	
		C137	WEERATNA et al., Reduction of antigen expression from DNA vaccines by coadministered oligodeoxynucleotides. Antisense Nucleic Acid Drug Dev. 1998 Aug;8(4):351-6.	
		C138	WEINER et al., Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization. Proc Natl Acad Sci U S A. 1997 Sep 30;94(20):10833-7.	
		C139	WHALEN et al., DNA-mediated immunization to the hepatitis B surface antigen. Activation and entrainment of the immune response. Ann N Y Acad Sci. 1995 Nov 27;772:64-76.	
		C140	WHITESELL et al., Stability, clearance, and disposition of intraventricularly administered oligodeoxynucleotides: implications for therapeutic application within the central nervous system. Proc Natl Acad Sci U S A. 1993 May 15;90(10):4665-9.	
		C141	YEW et al., Contribution of plasmid DNA to inflammation in the lung after administration of cationic lipid:pDNA complexes. Hum Gene Ther. 1999 Jan 20;10:223-34.	
		C142	YI et al. Rapid induction of mitogen-activated protein kinases by immune stimulatory CpG DNA. J Immunol. 1998 Nov 1;161(9):4493-7.	
		C143	YI et al., CpG DNA rescue of murine B lymphoma cells from anti-IgM-induced growth arrest and programmed cell death is associated with increased expression of c-myc and bcl-xL. J Immunol. 1996 Dec 1;157(11):4918-25.	
		C144	YI et al. CpG oligodeoxyribonucleotides rescue mature spleen B cells from spontaneous apoptosis and promote cell cycle entry. J Immunol. 1998 Jun 15;160(12):5898-906.	
	1	C145	ZHAO et al., Pattern and kinetics of cytokine production following administration of phosphorothioate oligonucleotides in mice. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):495-502.	

EXAMINER:	DATE CONSIDERED:	1	1
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	·				December 18, 2001	CONFIRMATION	NO.: 8458
4	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICANT:	Davis et al.		
Sheet 12 of 12				GROUP ART UNI	T: 1648	EXAMINER:	Jeffrey S. Parkin
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	1	C146	ZHAO et al., Modulation of oligonucleotide-induced immune stimulation by cyclodextrin analogs. Biochem Pharmacol. 1996 Nov 22;52(10):1537-44.	
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